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08/918,407	08/26/1997	JACK A. ROTH	INGN:050/HYL	6010

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EXAMINER	
SANDALS, WILLIAM O	

ART UNIT	PAPER NUMBER
1636	30

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/918,407	Applicant(s) Roth et al.
	Examiner William Sandals	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 16, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-20, 22-26, 32-61, 77-79, 83-91, 96-101, 111, 112, 115-120, ar* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-20, 22-26, 32-61, 77-79, 83-91, 96-101, 111, 112, 115-120, and 12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *15, 28*

18) ☒ Interview Summary (PTO-413) Paper No(s). *29*

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Response to Arguments

1. An interview with Gina Shishima, Esq. on May 16, 2001 resulted in a reconsideration of the previous office action mailed April 24, 2001.

2. In view of the amendments filed on May 22, 2000, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Information Disclosure Statement

3. The information disclosure statement filed April 24, 2001 fails to comply with 37 CFR 1.98(a)(3) because the citation was not accompanied by any comment or discussion concerning the relevancy of the patents and printed publications. The information disclosure of ninety six

references does not include a concise explanation of the relevance, as it is presently understood by the individual applicant, of the content of the information of each patent listed and non-patent document listed among the ninety six cited documents. Discovery of the relevant citations within this large group of documents cannot be reasonably ascertained lacking comment by applicant on the relevancy of the cited documents. The Information Disclosure Statement has been placed in the application file, but the information referred to therein has not been considered.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-20, 22-26, 46-61, 77-79, 83-91, 96-101, 111-120 and 127-130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-105 of U.S. Patent No. 5,747,469. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to

a method of reducing the growth rate of a tumor, which according to the specification is accomplished by cell death of the cells of the tumor. The claims of U.S. Patent No. 5,747,469 are drawn to a method of killing cells of a tumor. While the language of the instant claimed invention does not recite cell death, it is the only means taught by the instant specification to the claimed reduction of tumor growth rate. Therefore, the methods are accomplished through the same means and the subject matter of the claims is obviously the same.

6. Claims 1-20, 22-26, 46-61, 77-79, 83-91, 96-101, 111-120 and 127-130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of U.S. Patent No. 6,069,134. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of reducing the growth rate of a tumor, which according to the specification is accomplished by cell death of the cells of the tumor. The claims of U.S. Patent No.6,069,134 are drawn to a method of killing cells of a tumor. While the language of the instant claimed invention does not recite cell death, it is the only means taught by the instant specification to the claimed reduction of tumor growth rate. Therefore, the methods are accomplished through the same means and the subject matter of the claims is obviously the same.

Claim Objections

7. Claim 38 is objected to because of the following informalities: claim 38 recites "wherein said recombinant vector is a recombinant adenonviral vector is present". This language is confusing to read because the section which recites "said recombinant vector" seems to be superfluous. Deleting "recombinant vector is a" from the passage would correct this defect. Appropriate correction is required.

8. Claim 101 is objected to because it depends from canceled claim 95. For the purposes of examination it is assumed that claim 101 depends from claim 97.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-20, 22-26, 46-61, 77-79, 83-91, 96-101, 111, 112, 115-120, 128-130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing the growth rate of a tumor cell by the introduction of gene encoding a wild type p53 protein in a mouse model, does not reasonably provide enablement for a method of reducing the growth rate of a tumor by introducing any p53-expressing gene which encodes a functional p53 protein into a tumor while exposing the tumor to a DNA damaging agent in a non-mouse model animal. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are drawn to a method of reducing the growth rate of a tumor by introducing any p53-expressing gene which encodes a functional p53 protein into a tumor while exposing the tumor to a DNA damaging agent. The combination then inhibits the growth of the tumor cells.

a- The amount of experimentation required to practice the invention in the full scope of the claims would involve the development of a method for treatment of tumors in an non-mouse model animal with a gene expressing a non-wild type p53 and a DNA damaging agent.

b- There are only working examples provided for the use of a wild type p53 gene which expresses a wild type p53 protein, and only limited prophetic guidance which does not provide enabling teaching for the use of any p53-expressing gene which encodes any functional p53 protein, and there are only working examples provided in a mouse model system, and only limited prophetic guidance which does not provide a nexus between the mouse model system and any other animal.

c- The nature of the invention is complex. Gene therapy is a new and developing art as recited in Marshall in the section titled "The trouble with vectors", and at page 1054, column 3, and at page 1055, column 3. The problems of gene delivery, gene targeting to reach the intended host cell, and then to reach the intracellular target are not yet solved, as taught in Verma et al. (see especially page 239, column 3, the box titled "What makes an ideal vector?" and page 242).

d- The prior art taught by Orkin et al. (see especially the section on "Gene transfer and expression" and "Gene therapy in man status of the field") described many problems in the developing field of gene therapy. Recited problems include: lack of efficacy, adverse short term effects and limited clinical experience, the inability to extrapolate experimental results and unreliability of animal models. Problems with the vector include: host immune response to the vector and the expressed product, difficulty of targeting the vector to the desired site, transient expression of the gene of interest and low efficiency of delivery of the vector to the targeted site.

f- The state of the art as taught by Verma et al., which states "the problems - such as the lack of efficient delivery systems, lack of sustained expression, and host immune reactions - remain formidable problems" and Anderson, W. F. (see page 25, top of column 1), which states "[e]xcept for anecdotal reports of individual patients being helped, there is still no conclusive evidence that a gene-therapy protocol has been successful in the treatment of human disease". Further, the state of the art at the time of filing of the instant claimed invention was still developing and limited guidance was provided by the instant specification and claims. Levine at page 228, column 1 states that a p53 protein may act as a tumor suppressor (as instantly claimed) or may act as an oncogene which promotes the growth of a tumor. Levine goes on to teach at page 232, column 2, that mutations in p53 allow the growth of a tumor when cells are exposed to a DNA damaging agent, and that wild type p53 acts as a tumor suppressor when cells are exposed to a DNA damaging agent.

g- Given the teachings of Levine regarding the tumor suppressor activity of wild type p53 and that mutant p53 allows the growth of tumors exposed to DNA damaging agents, no prior art teachings would instruct one of skill in the art how to make or use any non-wild type p53 expressing gene in the instant method.

h- No teachings are found in the instant claims or specification to instruct one of skill in the art as to how to use a non-wild type p53 expressing gene in the instant claimed invention.

I- Therefore, given the analysis above, it must be considered that the skilled artisan would have needed to have practiced considerable non-routine, trial and error experimentation to enable the full scope of the claims. (all references are of record)

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-20, 22-26, 32-61, 77-79, 83-91, 111, 112, 115-120 and 128-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: claim 1 is drawn to a method of reducing the growth rate of a

tumor by contacting a cell within the tumor with a gene encoding a functional p53 protein and a DNA damaging agent. No step is provided for the expression of the p53 gene.

14. Claims 2-3, 33, 34 and 39 are rejected because there is no clear nexus between the "DNA damaging agent" of claim 1 and the list provided in claim 2. A link between the "DNA damaging agent" of claim 1 which states that the list provided in claim 2 is in fact a list of "DNA damaging agents" would cure this defect. For purposes of examination, it is assumed that there is a nexus between the claimed elements.

15. Claim 4 recites a recombinant vector that expresses a functional p53 protein in said cell, which depends from the claim 1 which recites a gene encoding a functional p53 protein. It is not clear how the two may be the same of may be different, and as such the claim is vague and indefinite.

16. Claims 4-11, 19, 20, 25, 33-39, 77-79, 128-130 are unclear because claim 4 recites a recombinant vector that expressed a functional p53 protein. There is no linking language to relate that the "p53 gene" of independent claim 1 is the same as the "expressed functional p53 functional protein" of claim 4. A clear statement which links or distinguishes between the two elements is necessary to clarify the claim. For purposes of examination, it is assumed that the claimed elements of claims 1 and 4 are the same element.

17. Claim 5 recites the limitation "said p53-expressing recombinant" in line 1. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 5 recites a "plasmid **or** (emphasis added) a plasmid within a liposome , a retroviral vector, an AAV vector, **or** (emphasis added) a recombinant adenoviral vector". The use of "or" in the two locations provides an ambiguity as to what is being claimed. It is not clear what is meant by these limitations, since one would not know whether it is one limitation or the other limitation, or both, which is intended to be part of the claim.

19. Claim 6 recites the limitation "said p53-expressing recombinant" in line 1. There is insufficient antecedent basis for this limitation in the claim.

20. Claim 7 recites the limitation "said p53-expressing recombinant" in line 1. There is insufficient antecedent basis for this limitation in the claim.

21. Claim 8 recites the limitation "the cytomegalovirus" in line 2. There is insufficient antecedent basis for this limitation in the claim.

22. Claim 8 recites the limitation "the SV40 early polyadenylation signal" in line 2. There is insufficient antecedent basis for this limitation in the claim.

23. Claim 9 recites the limitation "the p53 expression region" in line 2. There is insufficient antecedent basis for this limitation in the claim.

24. Claim 10 recites the limitation "the p53 expression region" in line 2. There is insufficient antecedent basis for this limitation in the claim.

25. Claim 10 recites the limitation "the EIA and EIB regions" in line 1. There is insufficient antecedent basis for this limitation in the claim.

26. Claims 11, 38, 39, 45 and 39 recite the limitation "a recombinant adenoviral vector is present within a recombinant adenovirus". It is unclear how an adenovirus vector is different from the adenovirus since the two elements would intuitively be one in the same.

27. Claim 22 recites the limitation "said tumor cell" in line 1. There is insufficient antecedent basis for this limitation in the claim.

28. Claim 26 recites the limitation "said tumor cell" in line 1. There is insufficient antecedent basis for this limitation in the claim.

29. Claims 51-61, 115-118 are dependent upon claim 1, claims 52-61 are dependent upon claim 51. Claim 1 recites a "DNA damaging agent". Claim 51 recites a "DNA damaging compound". It is unclear how the "DNA damaging compound" of claim 51 relates to the "DNA damaging agent" of independent claim 1 and further dependent claims 52-61, 115-118. Is the "DNA damaging compound" the same as the "DNA damaging agent" or some other entity? For purposes of examination, it is assumed that the claimed elements are the same.

30. Claims 86-91 recite the limitation "the period" in line 1. There is insufficient antecedent basis for this limitation in the claim.

31. Claim 101 recites the limitation "said lung cancer cell is a small cell lung carcinoma cell". Base claim 97 recites "said lung cancer cell is a non-small cell lung carcinoma cell". The claims are contradictory, making claim 101 vague and indefinite.

32. Claim 119 recites the limitation "the x-ray dosage" in line 1. There is insufficient antecedent basis for this limitation in the claim.

33. Claim 120 recites the limitation "the x-ray dosage" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

34. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

35. Claim 32 is rejected under 35 U.S.C. 102(a) as being anticipated by Tishler et al. (of record).

Tishler et al. taught (see the entire article) a composition comprising a gene encoding a functional p53 polypeptide in combination with a DNA damaging agent.

36. Claim 32 is rejected under 35 U.S.C. 102(a) as being anticipated by Clarke et al. (of record).

Clarke et al. taught (see the entire article) a composition comprising a gene encoding a functional p53 polypeptide in combination with a DNA damaging agent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

37. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Lane.

Lane taught (see the entire article) a composition comprising a gene encoding a functional p53 polypeptide in combination with a DNA damaging agent.

Claim Rejections - 35 USC § 103

38. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

39. Claims 32-36 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane in view of Tishler et al., Kastan et al. and Kuerbitz et al.

Lane taught the invention as described above under 35 USC 103.

Lane did not teach that the gene encoding a functional p53 polypeptide was contained in a plasmid, nor did Lane teach that the DNA damaging agent was a compound listed in claim 33.

Tishler et al. taught (see especially the abstract and page 2215) the expression of p53 polypeptide in combination with a list of DNA damaging agents.

Kuerbitz et al. taught (see especially materials and methods, figure 4 and the last paragraph) a composition comprising a gene encoding a functional p53 polypeptide in combination with a DNA damaging agent where the p53 gene was on a plasmid which was introduced into target cells along with a DNA damaging agent.

Kastan et al. taught (see especially the abstract, introduction and figures) a composition comprising a gene encoding a functional p53 polypeptide in combination with a DNA damaging agent, and that the loss of wild type p53 gene expression in a cell leads to cellular proliferation in cells exposed to DNA damaging agents.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant invention to combine the teachings of Lane with the teachings of Tishler et al., Kastan et al. and Kuerbitz et al. because Lane taught the introduction of p53 expressing genes into cells and Lane taught the expression of p53 in a cell in combination with DNA damaging agents in a method to treat tumors by killing the cells of the tumor which are so treated. Tishler et al., Kastan et al. and Kuerbitz et al. each taught the killing of cells by expressing p53 polypeptide in combination with a DNA damaging agent, where Tishler et al. taught the list of DNA damaging agents, and Kuerbitz et al. taught a composition of an expressed gene encoding a p53 polypeptide from a plasmid which was introduced into the target cell.

One of ordinary skill in the art would have been motivated to combine the teachings of Lane with the teachings of Tishler et al., Kastan et al. and Kuerbitz et al. because each of Lane, Tishler et al., Kastan et al. and Kuerbitz et al. taught the advantageous and desirable use of a

composition comprising an expressed gene encoding a p53 polypeptide in a cell in combination with DNA damaging agents which may be used in a method to kill the cells of a tumor with the composition. Tishler et al. taught the list of DNA damaging agents, and Kuerbitz et al. taught the a gene encoding p53 from a plasmid which was introduced into the target cell along with a DNA damaging agent. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Lane with Tishler et al., Kastan et al. and Kuerbitz et al.

40. Claims 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane, Tishler et al., Kastan et al. and Kuerbitz et al. as applied to claims 32-36 and 39-41 above, and further in view of Bacchetti et al.

Tishler et al., Kastan et al. and Kuerbitz et al. taught the invention as described above.

Tishler et al., Kastan et al. and Kuerbitz et al. did not teach that the gene encoding p53 was contained in an adenoviral vector.

Bacchetti et al. taught (see the abstract) the well known use of adenoviral vectors to express a p53 gene.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant invention to combine the teachings of Lane, Tishler et al., Kastan et al. and Kuerbitz et al. with the teachings of Bacchetti et al. because Bacchetti et al. taught the well known use of an adenoviral vector for expression of p53 in a cell. It would have been obvious to one of ordinary

skill in the art to substitute the well known adenoviral vector of Bacchetti et al. for the plasmid vector of Kuerbitz et al. to provide an expressed p53 gene to the target cell.

One of ordinary skill in the art would have been motivated to combine the teachings of Lane, Tishler et al., Kastan et al. and Kuerbitz et al. because Bacchetti et al. taught the advantageous and desirable use of an adenoviral vector which expressed high levels of the gene encoding a p53 polypeptide in a cell. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Lane, Tishler et al., Kastan et al. and Kuerbitz et al. with Bacchetti et al.

41. Claims 32-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane, Tishler et al., Kastan et al., Kuerbitz et al. and Bacchetti et al. as applied to claims 32-41 above, and further in view of the Stratagene Catalogue.

Lane, Tishler et al., Kastan et al. and Kuerbitz et al. and Bacchetti et al. taught the invention as described above.

Lane, Tishler et al., Kastan et al. and Kuerbitz et al. and Bacchetti et al. did not teach the composition in a kit.

Stratagene catalog teaches "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the

unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the advantageous and desirable use of a composition comprising an expressed gene encoding a p53 polypeptide in a cell in combination with DNA damaging agents which may be used in a method to kill the cells of a tumor with the composition into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches the desirability and advantages for combining reagents of use in an assay into a kit.

One of skill in the art would have been motivated to combine the teachings of Lane, Tishler et al., Kastan et al., Kuerbitz et al. and Bacchetti et al. with the teachings of the Stratagene catalogue since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit as recited above. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Lane, Tishler et al., Kastan et al., Kuerbitz et al. and Bacchetti et al. with the Stratagene Catalogue.

Conclusion

42. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.
Examiner
October 23, 2001

TERRY MCKELVEY
PRIMARY EXAMINER